#### **REMARKS**

Claims 1-9 are pending in this application. The Office Action objects to the specification; rejects claims 1-9 under 35 U.S.C. §112, first paragraph; and rejects claims 1-9 under 35 U.S.C. §102(e). By this Amendment, claims 1-9 are amended to recite methods of treating mitochondrial disease. Support for this amendment may be found in the present specification at, for example, paragraph 0016. No new matter is added.

## I. Objection to the Specification

The specification is objected to on the basis that an acronym was used without first disclosing the full name to which the acronym refers. By this Amendment, substitute paragraph 0003 is presented which states that the acronym MELAS stands for "mitochondrial encephalopathy, lactic acidosis and stoke."

Reconsideration and withdrawal of the objection are respectfully requested.

### II. Rejection under 35 U.S.C. §112, first paragraph

Claims 1-9 are rejected under 35 U.S.C. §112, first paragraph for failure to comply with the written description requirement. Specifically, the Office Action states that "the specification fails to clearly define mitochondrial disease." Applicant respectfully traverses the rejection.

Applicant respectfully submits that the definition of mitochondrial disease is clearly stated in the present specification at least at paragraphs 0005-0008. Specifically, mitochondrial diseases are those disorders of the body in which "mitochondria are abnormal in their shape, function and DNA."

Furthermore, Applicant submits that the phrase "mitochondrial disease" is one that is well known and widely understood among persons having ordinary skill in the art. See, for example, the reference cited in the Office Action "The Neurology of Mitochondrial DNA disease."

Accordingly, the claims satisfy the requirements of 35 U.S.C. §112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

# III. Rejection under 35 U.S.C. §102(e)

Claims 1-9 are rejected under 35 U.S.C. §102(e) as being anticipated by Fukumi et al. (Japanese Patent Publication No. 2003-335664). Applicant respectfully traverses the rejection with respect to the amended claims.

The cited reference discloses a composition comprising L-arginine and 0.2 to 20 parts by weight of L-ascorbic acid per 1 part by weight of L-arginine (abstract). This composition is a nutritional supplement (abstract), and is used to prevent cerebrospinal-system neurotrophy (claim 6).

However, the cited reference does not disclose the features of the amended claims. The cited reference at least fails to disclose a method of treating mitochondrial disease by administering an agent comprising L-arginine and 0.2 to 20 parts by weight of L-ascorbic acid per 1 part by weight of L-arginine. See the present specification at, for example, paragraph 0016. Instead, the cited reference only discloses preventing cerebrospinal-system neurotrophy by preventing an imbalance between lysine and arginine (paragraph 0005). The cited reference does not disclose any relation to mitochondria. Applicant respectfully submits that preventing an imbalance of amino acids is very different from a method of treating mitochondrial disease. Therefore, the cited reference does not anticipate the amended claims.

Reconsideration and withdrawal of the rejection are respectfully requested.

### IV. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

James A. Oliff

Registration No. 27,075

Samuel T. Dangremond Registration No. 60,466

JAO:STD/axl

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